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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/539,952	03/06/2006	Ingo Haeberlein	59181US004	8655

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EXAMINER	
MAEWALL, SNIGDHA	

ART UNIT	PAPER NUMBER
1612	

NOTIFICATION DATE	DELIVERY MODE
03/29/2011	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/539,952	HAEBERLEIN ET AL.	
	Examiner	Art Unit	
	Snigdha Maewall	1612	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 June 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-26 and 28- 34* is/are pending in the application.

4a) Of the above claim(s) *31-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17-26,28-30,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *11/11/10 and 12/09/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Receipt of applicant's arguments and amended claims and **RCE** filed on 06/21/10 is acknowledged.

Receipt of IDS filed on 11/11/10 and 12/09/10 is also acknowledged.

Claims 1-16 and 27 remain cancelled. Claims 31-32 remain withdrawn.

Accordingly, claims **17-26, 28-30 and 33-34** are under prosecution.

The rejections not reiterated herein have been withdrawn in light of applicant's amendments to claims.

Claim Rejections - 35 USC § 103

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 17-26, 28-30 and 33-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pflug etal. (WO 98/48766) in view of Geistlich et al (USP 4,096,241).

Polymerizable dental materials having an antimicrobial effect are provided. These include dental materials such as protective dental varnishes, composites, compomers, fissure sealants, dental cements, dental bonding agents and similar materials, and containing triclosan (abstract).

The dental materials according to the invention preferably contain a matrix of curable or hardenable resin material or materials. Such materials include for example, **methacrylate** compounds**, urethane compounds** and the like. Any conventional dental resin or curable dental matrix material is within the scope of the invention. The dental materials may also contain fillers, fluoride, stabilizers, **initiators,** solvents and other substances conventionally used in dental materials (paragraph bridging pages 6

and 7). In the curable dental materials described in this invention, the antimicrobial agent **triclosan** is embedded in a polymeric matrix. This provides the dental materials with a long-lasting antimicrobial effect as the triclosan cannot leach out of these materials quickly (page 7, last paragraph). Example 3 teaches an example of the invention which comprises 2%, 4%, 6%, 8%, 10% or 15% Triclosan, **4.8 % PENTA (polymerizable material) and 0.2 wt% camphorquinone (initiator).**

While WO teaches antimicrobial triclosan, WO does not expressly teach the antimicrobial agent taurolidine.

The secondary reference discloses preparations for the treatment and for prophylaxis of tooth and gum infections (col. 1, ll. 4-6). The preparation effectiveness is due to the unique action of the compounds concerned not only against bacteria but also against the toxins produced by the bacteria. The antimicrobial of choice is **taurolidine in** view of its extremely low toxicity over long periods of time (col. 1, ll. 65-68).

Generally, it is prima facie obvious to select a known material for incorporation into a composition, based on its recognized suitability for its intended purpose. *MPEP § 2144.07.* Accordingly, it would have been obvious to use taurolidine of the secondary reference as the antimicrobial agent of the primary reference. The motivation would be the reasonable expectation of making the polymerizable dental materials of the primary reference and maintaining antimicrobial properties by using another known antimicrobial agent. Additional motivation would have been to use an antimicrobial known to have low toxicity over long periods of time. It is obvious that the substance would naturally be

enriched as claimed in claim 19 and 20 and the mechanisms claimed would be obvious since prior art makes the composition obvious absent evidence to contrary.

Applicant's Arguments

Applicant's arguments filed 06/01/10 have been fully considered but they are not persuasive.

Applicant argues that that combining Pflug et al. and Geistlich et al. is not obvious. Geistlich et al. disclose oral care compositions, but not those with curable or hardenable compositions (e.g., "polymerizable component" in claims 17, 33, and 34) and thus one of skill in the art would not have had a reasonable expectation of success. For example, one of skill in the art would not have expected that the curable compositions of Pflug et al. would still be curable and that the curing mechanism would not be negatively affected by the addition of Geistlich et al.'s taurolidine. Moreover, one of skill in the art would not have expected that taurolidine would still be effective when added to the curable compositions of Pflug et al. It may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance

would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash).

Applicant argues that surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine. Further, Pflug et al. describe triclosan as being "soluble in many organic solvents [and] stable to hydrolysis" (page 4, lines 3-5). In contrast, Geistlich et al. describe taurolidine as a formaldehyde carrier (column 1, lines 28-29) and, thus, is not stable to hydrolysis. If the Examiner needs evidence of this, it can be provided upon request. Pflug et al. disclose that low water solubility is advantageous: "As the water solubility of triclosan is low and it is embedded in a crosslinked polymer matrix, leaching of the triclosan is low, resulting in a long-term antimicrobial effect." (Page 6, lines 1-4, emphasis added; *see also* page 7, lines 16-21.) Thus, Pflug et al. effectively teach away from the use of taurolidine, which is water soluble. If the Examiner needs evidence of this, it can be provided upon request. Further, in contrast, Geistlich et al. disclose use of taurolidine in toothpastes, tooth gels, and mouth washes (column 2, lines 28-32), not embedded in a polymeric matrix.

Applicant's arguments are not persuasive because Geistlich has been cited for an antibacterial substance such as taurolidine and whether being used with curable and hardenable compositions is an intended use which does not hold patentable weight

wherein the claims are drawn to dental material. Claims are drawn to dental material and application of dental material is an intended use which does not hold patentable weight. Prior art teaches taurolidine, an antimicrobial agent and motivation to combine with primary reference is for its low toxicity properties as discussed in the rejection above. Prior art teaches compatibility for oral applications, therefore one of ordinary could utilize the compound taurolidine in dental curable composition. The art pertains to same field of endeavor and is an analogous art and thus utilization of taurolidine for bactericidal efficacy would have been obvious to one of ordinary skill in that art at the time of instant invention. Regarding the different mechanisms used by triclosan and taurolidine, it is the position of the examiner that no evidence has been provided by the applicants.

Applicant further argues that it may not be necessarily concluded that if one takes a substance (e.g., taurolidine) that has been used in non-curable compositions (e.g., mouthwashes, dentrifices, etc.), then that substance can also be used in curable compositions. When a substance is put into a curable composition, the substance will typically remain within the composition, especially if the composition is cured. Thus, it would be expected that the efficacy of the substance would be dramatically reduced (e.g., as compared to the substance in a liquid composition, such as mouthwash). Surprisingly, Applicants found that a substance (e.g., taurolidine) whose bacteriostatic and/or bactericidal efficacy is formed in the presence of intraoral microorganisms may be incorporated into a curable composition. Moreover, the structure of Geistlich et al.'s taurolidine is very much different from that of Pflug et al.'s triclosan and, thus, it may be

assumed that the mechanism used by triclosan to kill germs may be different from that used by taurolidine. The Examiner, in simply stating that it would have been obvious to exchange Pflug et al.'s triclosan with Geistlich et al.'s taurolidine, has not provided adequate and proper reasoning sufficient to establish a primafacie case of obviousness. Once the solution to a problem is known, one can be tempted to import hindsight and allege it is obvious. Thus, Applicants respectfully submit that the Examiner's combination of Pflug et al. in view of Geistlich et al. must have been as a result of improper hindsight analysis.

These arguments are not persuasive. Instant claims are drawn to dental material and application of dental material is an intended use which does not hold patentable weight. Claims recite dental material which can be broadly interpreted as mouth rinse or mouthwashes or dentifrices. The claims do not recite method of using taurolidine in curable composition; the claims are drawn to dental material and Prior art teaches taurolidine, an antimicrobial agent and motivation to combine with primary reference is for its low toxicity properties as discussed in the rejection above. Prior art teaches compatibility for oral applications, therefore one of ordinary could utilize the compound taurolidine in dental curable composition. The art pertains to same field of endeavor and is an analogous art and thus utilization of taurolidine for bactericidal efficacy would have been obvious to one of ordinary skill in that art at the time of instant invention. Therefore the argued surprising utilization of taurolidine in curable composition is an intended functional use wherein the claims are drawn to a dental material. Besides the argued

differences regarding curable material is not reflected in claims thus the results do not commensurate with the scope of instant claims.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Snigdha Maewall whose telephone number is 571-272-6197. The examiner can normally be reached on Monday - Friday from 8:30 - 5:00 PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frederick Krass can be reached on (571) 272-0580. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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/Snigdha Maewall/
Examiner, Art Unit 1612
/Gollamudi S. Kishore/
Primary Examiner, Art Unit 1612